AUG 1 5 2002

K021719
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Safety and Effectiveness Information

Submitted By:

David M. Hooper, PhD
Manager, Clinical & Regulatory Affairs
Spinal Concepts, Inc.
12012 Technology Blvd., Suite 100
Austin, TX 78727
512-918-2700
May 22, 2001

Device:

Trade Name:	Fortitude Cement Restrictor
Proposed Classification Name:	Prosthesis, Hip, Cement Restrictor
Product Code:	JDK (21CFR 878.3300)

Predicate Devices:

The Fortitude Cement Restrictor is similar in terms of intended use, materials of construction, and technological characteristics to the predicate devices reviewed, the Medtronic Sofamor Danek Cement Restrictor(s) (K012255 and K013014) and the Signus RABEA™ Cement Restrictor (K990345).

Device Description:

The Fortitude Cement Restrictor is a hollow, titanium alloy device with teeth on two opposing flat sides. The device comes in various sizes and is offered in straight and tapered styles. The device is used to hold bone cement (PMMA) in the distal diaphyseal canal in patients requiring a cemented arthroplasty device.

Intended Use:

The Fortitude Cement Restrictor System is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for use in spinal applications.

Substantial Equivalence:

The Fortitude Cement Restrictor was demonstrated to be substantially equivalent to previously cleared devices such as the Medtronic Sofamor Danek Cement Restrictor(s) (K012255 and K013014) and the Signus RABEA™ Cement Restrictor (K990345). A Design Review for the device was provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2002

David Hooper, Ph.D.
Manager, Clinical & Regulatory Affairs
Spinal Concepts Incorporated
12012 Technology Blvd, Suite 100
Austin, Texas 78727

Re: K021719
Fortitude Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: May 22, 2002
Received: May 23, 2002

Dear Dr. Hooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

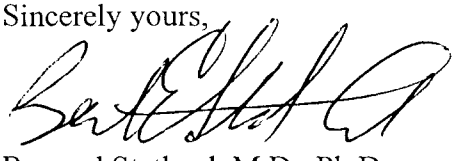
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address:
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bernard Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INIDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021719

Device Name: Spinal Concepts, Inc. **Fortitude Cement Restrictor**

Indications for Use:

The Fortitude Cement Restrictor System is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for use in spinal applications.

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021719

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)